

REMARKS/ARGUMENTS

Reconsideration is respectfully requested in light of the claim amendments and remarks which follow. Claims 1, 11, 20, 29, 42, and 43 have been amended. Support for the amendment of claims 1 and 20 may be found for example in the specification at paragraphs 0056-0058 and 0064-0067. Support for the amendment of claims 42 and 43 may be found for example in the specification at page 8, lines 2-3, and at paragraphs 0056-0058 and 0064-0067. Claims 11 and 29 have been amended for clarity. Upon entry of this amendment, claims 1-43 are pending for examination.

Restriction Requirement

Applicants acknowledge the Examiner's decision to consider all the claims together in response to Applicants' traverse of the restriction requirement.

Claim Objections

The Examiner has objected to claims 1-43 because of the alleged informality on page 2 of the previous response to the restriction requirement, in which all claims were listed under "Amendments to the Claims", while all claims were labeled "(original)" and no claim was listed as "(amended)". The present response contains claims that have been amended; thus the heading "Amendments to the Claims" is appropriate in the present response.

Claim rejections under 35 U.S.C. § 112, second paragraph - definiteness

Claims 1-43 stand rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness.

(a) Claim 1

The Examiner alleges that the claims are unclear as to the location of the polymer and biological material in relation to the nanofiber and in relation to each other. In making this rejection, the Examiner states "[t]he claims should require the biological material to be incorporated into the nanofibers or attached to nanofibers as disclosed in the specification (page 11, paragraph 0058), and the nanofiber should be required to be formed from the polymer as disclosed in the specification (paragraphs 0056, 0057, and 0064-0067)". See Office Action at

page 2. In accordance with the Examiner's suggestion, claim 1 has been amended to recite that "the biological material is attached to the nanofiber or incorporated into the nanofiber, and wherein the nanofiber is formed from said first polymer ". Accordingly, Applicants request withdrawal of this aspect of the rejection under 35 U.S.C. § 112, second paragraph.

(b) Claim 11

The Examiner alleges that in claim 11 the recitation of "polyacrylamide (PAM) as non-ionic" is unclear. *See* Office Action at page 3. Solely for the purposes of clarification, the recitation "non-ionic" has been deleted in this claim. Accordingly, Applicants request withdrawal of this aspect of the rejection under 35 U.S.C. § 112, second paragraph.

(c) Claim 20

The Examiner alleges that "[i]n claim 20 and other claims that require a second polymer, the relationship of the second polymer to the first polymer, biological material and nanofiber is unclear". *See* Office Action at page 3. In accordance with the Examiner's suggestion, claim 1 has been amended to recite that "the biological material is attached to the nanofiber or incorporated into the nanofiber, and wherein the nanofiber is formed from said first polymer ". Furthermore, claim 20, which depends from claim 1, has been amended to recite that "the nanofiber is formed from said first and second polymer." Accordingly, Applicants request withdrawal of this aspect of the rejection under 35 U.S.C. § 112, second paragraph.

(d) Claim 29

The Examiner alleges that claim 29 is unclear by requiring polysaccharides and cellulose as both a synthetic organic polymer and a naturally occurring polymer. *See* Office Action at page 3. For clarity, Applicants have deleted polysaccharides, cellulose, and poly-L-lactide from the list of synthetic organic polymers recited in claim 29.

Claim rejections under 35 U.S.C. § 102(a)

Claims 42 and 43 stand rejected under 35 U.S.C. § 102(a) as being allegedly anticipated by Jia *et al.*, Biotechnol. Prog., 18: 1027-1032 (2002) ("Jia"). Claims 42 and 43 have been amended. To the extent that the rejection applies to the amended claims, Applicants traverse.

To anticipate a claim, a reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found . . . in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). *See, also*, MPEP 2131.

Claim 42 and 43 have been amended to recite, in part, that the claimed nanofiber "has a plurality of nanopores". In contrast to the presently claimed invention, Jia does not disclose or suggest nanofibers having nanopores; rather, Jia discloses a method of electrospinning that "initially resulted in the formation of beads on the fibers". After adding 0.5% LiCl during the electrospinning process, Jia was able to suppress the generation of beads, making reference to Figure 1 for an illustration of the resulting nanofiber. Upon examining Figure 1(A) in Jia, the skilled artisan would conclude that Jia discloses a nanofiber with a weaved structure internal structure, not a nanofiber "hav[ing] a plurality of nanopores", which are disclosed in the present specification as "a pore, hole, or depression on the surface of a fiber or nanofiber or a hole inside of a fiber or nanofiber". *See* specification at page 8, lines 8-9.

Because Jia does not teach each and every element of amended claims 42 and 43, this reference does not anticipate these claims. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(a).

Claim rejections under 35 U.S.C. § 103(a)

In order to establish a *prima facie* case of obviousness, three criteria must be met. "First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim

limitations". See MPEP 2142. All three elements set forth above must be present in order to establish a *prima facie* case of obviousness.

A. Jia in view of Wendorff

Claims 1-10, 12-18, 20-31, 38 and 39 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Jia in view of Wendorff *et al.* (U.S. Patent No. 6,790,528) ("Wendorff"). Applicants traverse.

In making this rejection, the Examiner alleges that "[i]t would have been obvious to provide the nanofibers of Jia *et al.* with nanopores to obtain a very large surface area as suggested by Wendorff *et al.* producing porous nanofibers . . .". See Office Action at page 5. Further, the Examiner notes that "Wendorff *et al.* is a 371 of a PCT published as WO 02/16680 on 2/28/02. This date is prior to the earliest date of 11/12/02 which the present application relies on for priority". See Office Action at page 6. Applicants provide the 37 C.F.R. § 1.131 affidavit of Dr. You-Lo Hsieh, an inventor of the present application, attesting to the conception and reduction to practice of the presently claimed invention *prior* to the PCT publication date of Wendorff on February 28, 2002 with this response¹. Accordingly, the claimed invention "was [not] . . . patented or described in a printed publication . . . before the invention thereof by the applicant for a patent", as required under 35 U.S.C. § 102(a). For this reason, Wendorff does not qualify as prior art to be used in making a 35 U.S.C. § 103(a) rejection.

As discussed in detail above, Jia does not teach a nanofiber "having a plurality of nanopores", as required by the present claims. Thus, Jia does not teach or suggest each and every element of the claimed invention as required to establish a *prima facie* case of obviousness. Accordingly, Applicants respectfully request withdrawal of this aspect of the rejection under 35 U.S.C. § 103(a).

¹ Applicants have included an unsigned affidavit with this response; when the signed affidavit becomes available, Applicants will promptly submit it.

B. Jia in view of Wendorff, further in view of Vann

Claims 11 and 40 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Jia in view of Wendorff, further in view of Vann (U.S. Patent No. 6,573,089) ("Vann"). Applicants traverse.

In making this rejection, the Examiner alleges that "[w]hen providing the nanofibers of Jia *et al.* with nanopores as set forth above, it would have been obvious to use *PEG as a linker* to attach the biological material to the nanofibers as suggested by Vann". (Emphasis added.) See Office Action at page 7.

As discussed above, Wendorff does not qualify under 35 U.S.C. § 102(a) as a prior art reference that can be used in setting forth an obviousness rejection. Neither of the remaining references, *i.e.*, Jia and Vann, teach or suggest a nanofiber "having a plurality of nanopores". Thus, the combination of the remaining cited references do not teach or suggest each and every element of the claimed invention as required to establish a *prima facie* case of obviousness. Accordingly, Applicants respectfully request withdrawal of this aspect of the rejection under 35 U.S.C. § 103(a).

C. Jia in view of Wendorff, further in view of Smith

Claim 19 stands rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Jia in view of Wendorff, further in view of Smith *et al.* (U.S. Patent No. 6,821,479) ("Smith"). Applicants traverse.

In making this rejection, the Examiner alleges "[w]hen providing the nanofibers of Jia *et al.* with nanopores as set forth above, it would have been obvious to *cross-link the polymer* used to form the nanofibers as suggested by Smith *et al.*" (Emphasis added.) See Office Action on page 7.

As discussed above, Wendorff does not qualify under 35 U.S.C. § 102(a) as a prior art reference that can be used in setting forth an obviousness rejection. Neither of the remaining references, *i.e.*, Jia and Smith, teach or suggest a nanofiber "having a plurality of nanopores". Thus, the combination of the remaining cited references do not teach or suggest each and every element of the claimed invention as required to establish a *prima facie* case of

obviousness. Accordingly, Applicants respectfully request withdrawal of this aspect of the rejection under 35 U.S.C. § 103(a).

D. Jia in view of Wendorff, further in view of Lockhart

Claim 41 stands rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Jia in view of Wendorff, further in view of Lockhart (U.S. Patent No. 6,974,673) ("Lockhart"). Applicants traverse.

In making this rejection, the Examiner alleges that "[w]hen providing the nanofibers of Jia *et al.* with nanopores as set forth above, it would have been obvious to use *PAA as a linker* to attach the enzyme to the nanofibers as suggested by Lockhart [as Lockhart] disclose[s] using PAA as a linker to attach a molecular constituent to a fiber." (Emphasis added.) See Office Action at page 7-8, bridging paragraph.

As discussed above, Wendorff does not qualify under 35 U.S.C. § 102(a) as a prior art reference that can be used in setting forth an obviousness rejection. Neither of the remaining references, *i.e.*, Jia and Lockhart, teach or suggest a nanofiber "having a plurality of nanopores". Thus, the combination of the remaining cited references do not teach or suggest each and every element of the claimed invention as required to establish a *prima facie* case of obviousness. Accordingly, Applicants respectfully request withdrawal of this aspect of the rejection under 35 U.S.C. § 103(a).

E. Jia in view of Wendorff, further in view of Chu

Claims 32-35 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Jia in view of Wendorff, further in view of Chu *et al.* (U.S. Patent No. 6,790,455) ("Chu"). Applicants traverse.

In making this rejection, the Examiner alleges that "[w]hen providing the nanofibers of Jia *et al.* with nanopores as set forth above, it would have been obvious to produce a *membrane* containing the nanofibers as suggested by Chu *et al.* to obtain the expected function of the membrane". (Emphasis added.) See Office Action at page 8.

As discussed above, Wendorff does not qualify under 35 U.S.C. § 102(a) as a prior art reference that can be used in setting forth an obviousness rejection. Neither of the

remaining references, *i.e.*, Jia and Chu, teach or suggest a nanofiber "having a plurality of nanopores". Thus, the combination of the remaining cited references do not teach or suggest each and every element of the claimed invention as required to establish a *prima facie* case of obviousness. Accordingly, Applicants respectfully request withdrawal of this aspect of the rejection under 35 U.S.C. § 103(a).

F. Jia in view of Wendorff, further in view of Chu and Vann

Claim 36 stands rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Jia in view of Wendorff, further in view of Chu and Vann. Applicants traverse.

In making this rejection, the Examiner alleges that "[w]hen providing the nanofibers of Jia *et al.* with nanopores and providing a *membrane* comprising the nanofibers as set forth above [in Chu], it would have been obvious to use *PAA as a linker* to attach the enzyme to the nanofibers as suggested by Lockhart . . .". (Emphasis added.) See Office Action at page 9.

As discussed above, Wendorff does not qualify under 35 U.S.C. § 102(a) as a prior art reference that can be used in setting forth an obviousness rejection. The remaining references, *i.e.*, Jia, Chu, and Vann, do not teach or suggest a nanofiber "having a plurality of nanopores". Thus, the combination of the remaining cited references do not teach or suggest each and every element of the claimed invention as required to establish a *prima facie* case of obviousness. Accordingly, Applicants respectfully request withdrawal of this aspect of the rejection under 35 U.S.C. § 103(a).

G. Jia in view of Wendorff, further in view of Chu and Lockhart

Claim 37 stands rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Jia in view of Wendorff, further in view of Chu and Lockhart. Applicants traverse.

In making this rejection, the Examiner alleges that "[w]hen providing the nanofibers of Jia *et al.* with nanopores and providing a membrane comprising the nanofibers as set forth above, it would have been obvious to use PAA as a linker to attach the enzyme to the nanofibers as suggested by Lockhart . . .". (Emphasis added.) See Office Action at page 9.

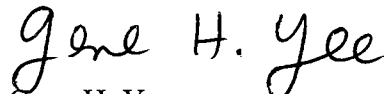
As discussed above, Wendorff does not qualify under 35 U.S.C. § 102(a) as a prior art reference that can be used in setting forth an obviousness rejection. The remaining references, *i.e.*, Jia, Chu, and Lockhart, do not teach or suggest a nanofiber "having a plurality of nanopores". Thus, the combination of the remaining cited references do not teach or suggest each and every element of the claimed invention as required to establish a *prima facie* case of obviousness. Accordingly, Applicants respectfully request withdrawal of this aspect of the rejection under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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